FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC)

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), Silver Spring, MD

January 30, 2013

QUESTIONS

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1. (**DISCUSSION)** Discuss the evidence to support the efficacy of dry powder mannitol (DPM) at a dose of 400 mg twice daily in improving pulmonary function in patients 6 years and older with cystic fibrosis.

2. **(DISCUSSION)** Discuss the overall safety profile of DPM.

3. **(DISCUSSION)** Discuss the support for efficacy and the safety profile of DPM in children and adolescents 6-17 years of age.

4. **(VOTE)** Considering the totality of the data, is there substantial evidence of efficacy for DPM at a dose of 400 mg twice daily for improvement of pulmonary function in patients 6 years and older with cystic fibrosis? If not, what further efficacy data should be obtained?

5. **(VOTE)** Is the safety profile for DPM for the maintenance treatment of patients with cystic fibrosis sufficient to support approval? If not, what further safety data should be obtained?

6. **(VOTE)** Do the efficacy and safety data provide substantial evidence to support approval of DPM at a dose of 400 mg twice daily for the management of cystic fibrosis in patients aged 6 years and older to improve pulmonary function? If not, what further data should be obtained?